

**REMARKS**

This Amendment is responsive to the Office Action mailed September 15, 2009. With this amendment, claims 18, 20, 22, and 25 have been amended, and claims 26-28 have been added. Claims 1-7 and 13-28 are pending. Claims 1-7, 13-17, and 20 are withdrawn. Claims 18-19 and 21-28 are under consideration. No new matter has been added. Support for the amendment can be found throughout the specification and claims as filed, including, e.g., at paragraph [0031] bridging pages 9-10, Example 1 on pages 29-31, and original claims 18-19.

Interview Summary

Applicant expresses appreciation for the courtesies extended by Examiner Ghali during a telephone call with Applicant's representative Walter Schlapkohl on March 10, 2010 regarding the above-identified application.

During the interview, Applicant's representative presented draft claim amendments which may be made in response to the outstanding Office Action mailed September 15, 2009. In addition, Applicant's representative discussed potential arguments and potential evidence which may be presented to demonstrate unexpected results in response to the obviousness rejections set forth in the outstanding Office Action. Examiner Ghali indicated that the draft claim amendments would obviate all of the rejections in the outstanding Office Action with the exception of the rejections under 35 U.S.C. §103. However, with respect to the obviousness rejections, the Examiner indicated that she would consider any claim amendments in view of any arguments and/or evidence presented in a written response.

The amendments as presented in the interview, and arguments directed thereto, are set forth herein.

In addition, Applicant's representative expressed to the Examiner a desire for Applicant's representatives to continue to conduct their representation with decorum and courtesy. Applicant's representative further requested that the Examiner inform Applicant's representatives if the Examiner perceives that they are proceeding without decorum and courtesy.

Applicant notes that the Examiner's Interview Summary indicates that data regarding ibuprofen and sesame oil "will be evaluated when filed." For completeness of the record, while data regarding ibuprofen and sesame oil may be filed supplemental to this response, Applicant submits that the instant amendment and remarks are responsive to the Office Action mailed September 15, 2009.

Applicant further notes that the Examiner's Interview Summary indicates that rejoinder of "withdrawn species isopropyl myristate" will be considered upon indication of the allowable subject matter. For completeness of the record, Applicant submits that "isopropyl myristate" is the elected species, and that "clarified sesame oil" is a withdrawn species (see, e.g., page 2, section 1, of the Office Action mailed March 26, 2008).

#### Restriction Requirement

The Office Action rejoins claim 25 among those claims considered by the Examiner.

In response, Applicant thanks the Examiner for reconsideration of the Requirement for Restriction with respect to claim 25. In addition, Applicant respectfully requests the Examiner to rejoin the non-elected claims (claims 1-7, 13-17, and 20) upon allowance of the elected subject

matter. In particular, Applicant respectfully requests that the Examiner reconsider the Requirement for Restriction with respect to Withdrawn-Currently Amended claim 20. Applicant submits that rejoinder of claim 20 with the elected subject matter at this stage of prosecution would not impose a search burden on the Examiner, and therefore respectfully requests rejoinder.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Office Action rejects claim 25 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Office Action alleges that the specification fails to support the claimed subject matter insofar as it recites a method of “treating at least one symptom as a result of transdermal delivery of an active ingredient” (see Office Action at page 4, first full paragraph).

In response, and without acquiescing to the propriety of the rejection, Applicant submits that the instant amendment is responsive to the present rejection. Applicant notes that the present amendment is also in accordance with the language found acceptable by the Examiner in the Interview of March 10, 2010 (see above) and fully responsive to the rejection set forth under 35 U.S.C. § 112, first paragraph. Applicant further submits that the claimed subject matter is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Based at least on the foregoing, Applicant respectfully requests reconsideration of the rejection under 35 U.S.C. § 112, first paragraph, and withdrawal of the same.

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

The Office Action rejects claims 19 and 25 under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

In response, and without acquiescing to the propriety of the rejection, Applicant submits that the instant amendment is responsive to the present rejections. Applicant notes that the present amendment is also in accordance with the language found acceptable by the Examiner in the Interview of March 10, 2010 (see above) and that the claimed subject matter is now even clearer and more definite.

Based at least on the foregoing, Applicant respectfully requests reconsideration of the rejections under 35 U.S.C. § 112, second paragraph, and withdrawal of the same.

Claim Rejections – 35 U.S.C. § 102(b)

The Office Action rejects claims 18, 22, and 23 under 35 U.S.C. § 102(b) as allegedly anticipated by Ramirez et al (U.S. Patent No. 5,342,535; hereinafter “Ramirez”).

In response, Applicant submits that the claimed subject matter is not anticipated by Ramirez. In particular, Applicant submits that Ramirez fails to teach “[a] method of treating and/or alleviating at least one of pain, aches, and inflammation comprising,

dissolving in a bath a pharmaceutical composition for transdermal delivery comprising:

at least one skin permeation enhancer comprising clarified sesame oil;

at least one effervescent agent; and

at least one active ingredient or pharmaceutically acceptable salt thereof comprising ibuprofen; and

immersing a body part of a human being to be treated in the bath containing the dissolved pharmaceutical composition.” For example, Ramirez fails to teach a composition comprising ibuprofen. Furthermore, Applicant notes that the present amendment is in accordance with the language found acceptable by the Examiner in the Interview of March 10, 2010 (see above) and fully responsive to the rejection set forth under 35 U.S.C. § 102(b).

Based at least on the foregoing, Applicant respectfully requests reconsideration of the rejection under 35 U.S.C. § 102(b) and withdrawal of the same.

Claim Rejections – 35 U.S.C. § 103(a)

The Office Action rejects claims 21, 24, and 25 under 35 U.S.C. § 103(a) as allegedly unpatentable over Ramirez.

In response, Applicant submits that the claimed subject matter is not unpatentable over Ramirez. In particular, Applicant submits that Ramirez fails to teach or suggest the claimed subject matter for at least the same reasons as set forth above with respect to the rejection under 35 U.S.C. § 102(b). For example, Ramirez fails to teach or suggest ibuprofen.

Accordingly, Applicant submits that the claimed subject matter is not unpatentable over Ramirez. Applicant respectfully requests reconsideration of the rejection under 35 U.S.C. § 103(a), and withdrawal of the same.

The Office Action also rejects claim 19 under 35 U.S.C. § 103(a) as allegedly unpatentable over the combination of Ramirez, Youssefeyeh (U.S. Patent App. Pub. 2001/0036489 A1; hereinafter “Youssefeyeh”), Sharma et al. (U.S. Patent No. 5,229,130;

hereinafter "Sharma") and Büyüktimkin et al. (U.S. Patent No. 6,083,996; hereinafter "Büyüktimkin").

In response, Applicant submits that the claimed subject matter is not unpatentable over Ramirez, Youssefyeh, Sharma, and/or Büyüktimkin, either alone or in combination. Initially, Applicant submits that none of the cited documents teaches or suggests "[a] method of treating and/or alleviating at least one of pain, aches, and inflammation comprising,

dissolving in a bath a pharmaceutical composition for transdermal delivery comprising:

at least one skin permeation enhancer comprising clarified sesame oil;

at least one effervescent agent; and

at least one active ingredient or pharmaceutically acceptable salt thereof comprising ibuprofen; and

immersing a body part of a human being to be treated in the bath containing the dissolved pharmaceutical composition." In particular, Applicant submits that the cited art, either alone or in combination, fails to suggest at least the particular combination of ibuprofen and clarified sesame oil in a composition for transdermal delivery.

For example, Ramirez teaches compositions containing Kurroll's salt used to increase the viscosity of water. However, Ramirez fails to teach or suggest a composition comprising ibuprofen. Ramirez also fails to teach or suggest a composition comprising sesame oil. Ramirez also fails to disclose a composition comprising a combination of ibuprofen and clarified sesame oil.

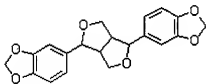
Youssefieh discloses anti-wrinkle preparations and methods for minimizing wrinkles in the face and neck areas. However, Youssefieh also fails to teach or suggest a composition comprising clarified sesame oil, or a combination of ibuprofen and clarified sesame oil.

Sharma discloses vegetable oil-based skin permeation enhancers, including sesame oil. However, Sharma also fails to teach or suggest a composition comprising a combination of ibuprofen and clarified sesame oil.

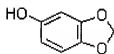
Büyüktimkin discloses aqueous pharmaceutical compositions of a semi-solid consistency for topical application. However, Büyüktimkin fails to teach or suggest a composition comprising a combination of ibuprofen and clarified sesame oil.

In contrast, Applicant submits that the presently claimed subject matter is directed to, *inter alia*, the use of a composition comprising clarified sesame seed oil and ibuprofen. Quite unexpectedly, the combination of sesame oil and ibuprofen in the presently claimed formulation provides an oil phase containing supersaturated ibuprofen. Applicant further submits that the supersaturation provides unexpectedly enhanced transdermal delivery potential.

Applicant notes that the monounsaturated and polyunsaturated fatty acids common to the other vegetable and nut oils are present in sesame oil in different proportions. Furthermore, unique to clarified sesame seed oil is the presence of unsaponifiables such as two natural antioxidants called sesamin and sesamol, the chemical structures of which appear below.



Sesamin



Sesamol

Not intending to be held to any one theory, Applicant understands that the presence of sesamin and sesamol help dissolve ibuprofen into the sesame oil and allow the dissolution of ibuprofen in sesame oil to a super-saturation point. In particular, Applicant submits that sesamin and sesamol contain a high degree of polarity and conjugated double bonds similar to ibuprofen that would enable solubilization on the classic theory of "like dissolves like." A third unsaponifiable species, called sesamoline, which in the present invention also may also assist in ibuprofen transdermal absorption through the skin.

Based at least on the foregoing, including the unexpectedly high saturation of ibuprofen and sesame oil, Applicant submits that the claimed subject matter is not unpatentable over Ramirez, Youssefyeh, Sharma, and/or Büyüktimkin, either alone or in combination. Applicant respectfully requests reconsideration of the rejection under 35 U.S.C. § 103(a), and withdrawal of the same.



### CONCLUSION

In view of the foregoing remarks and amendments, Applicant respectfully submits that the claims are in condition for allowance.

The U.S. Patent & Trademark Office is authorized to charge any required fee to Deposit Account No. 19-0089.

If there should be any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully Submitted,  
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